DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2009 has been entered.

Claim Objections

2. Claim 1 is objected to because of the following informalities: there is a typographical error in the word "phosophate" in line 4 of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112 – 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The amendment to the claim alters "mannitol, a binder solution of microcrystalline cellulose, calcium-phosphate dibasic, hydroxypropylmethylcellulose, water and ethanol" to "a binder consisting essentially of mannitol, calcium-phos[o]phate dibasic and hydroxypropylmethylcellulose". The omission of water and ethanol are not new matter as they are present in the solution to apply the other ingredients but absent or at least present in much lower quantities in the actual pharmaceutical formulation. The application as filed does not indicate mannitol is a binder but rather as an "excipient". The binder is exemplified as requiring microcrystalline cellulose, an element which is omitted from the binder in the current set of claims, calcium phosphate dibasic and hydroxypropylmethylcellulose. No where does the specification indicate that a binder can be prepared using only calcium phosphate dibasic and hydroxypropylmethylcellulose. Because of the specification teaching that the binder as requiring microcrystalline cellulose to be present in conjunction with calcium phosphate dibasic and hydroxypropylmethylcellulose and the failure to recognize mannitol as a binder, new matter is present in the instant claim.

If Applicant is in disagreement with the Examiner regarding support for the amended claim, Applicant is respectfully requested to point to page and line number wherein support may be found for the instant invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruepp et al. (DE 19639375) in view of Cook (US 5,567,438), Green (US 4,026,851) and Margolin et al. (US 2002/0045582). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed June 2, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Ruepp merely discloses a dry extract of the plant and not the claimed mistletoe extract. The rejection lacks support for a contention that the dry mistletoe extract of Ruepp is lectin extract; i.e. is enriched in lectins. The additional references do not teach mistletoe lectin extract and so fail to cure this deficiency.

These arguments are unpersuasive. The instant claim only recites "mistletoe lectin extract" as an ingredient and does not specify the process by which the extract is obtained. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Even if the process was recited in the claim, patentability would be determined based on the extract and not the process by which the extract was obtained (see MPEP 2113).

The instant specification states that a water extraction from mistletoe leaf, fruit and stem (p 16 of the specification). The process of Ruepp utilizes solvent extraction using water extraction (p 3, ¶ 5). It is also known in the art that mistletoe lectins are the

pharmacologically active constituent of mistletoe extracts (Mengs et al., p 1399, col 2, ¶ 3). Based on the same solvent being used to prepare the extracts and the knowledge that the pharmacologically active ingredient is lectins, the material used by Ruepp et al. meets the limitation of "mistletoe lectin extract" as recited in claim 1. Due to the difference in lectin content based on the source material and extraction method and desired pharmacologically effects, one of ordinary skill would optimize the amount of mistletoe lectin extract that is present in the dosage form.

The Examiner is interpreting the phrase "consisting essentially" as being equivalent to "comprising". For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) **MPEP 2111.03** Also, the preamble of the claim uses the transitional phrase "comprising", which does not limit the ingredients which may be present in the composition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW